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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,286	03/16/2004	Joachim Mierau	1/1472	3050

28519 7590 03/13/2007
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/801,286

Applicant(s)

MIERAU ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 9-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 9-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12-15-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed December 15, 2006 is acknowledged. Claims 1-4 and 6-8 are canceled. New claims 12-19 are presented. Accordingly, claims 5 and 9-19 are now under consideration.

A Brief Description of the Drawings and amendments to the Abstract are noted. Accordingly, the objection to the disclosure is withdrawn.

Claims 1-11 were provisionally rejected in the last Office Action on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/935508. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to reducing food intake comprising administering a dopamine receptor agonist of which pramipexole is an example.

Applicants argue the instant application has an effective U.S. filing date before the copending application, and a terminal disclaimer is only required in the later-filed application.

At which time the present rejection is the only remaining issue, it will be withdrawn. Presently, the rejection of record on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/935508, is maintained and extended to include new claims 12-19.

In the last Office Action claims 1-11 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to

Art Unit: 1614

reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. It was asserted Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. There are no working examples directed to administration of pramipexole wherein any outcome is noted for a patient population from 6 to 18 years old, and, optionally, having type 2 diabetes. Figures 1 and 2, pages 8 and 9, show a food intake reduction and a reduction in body weight following the administration of pramipexole. Support both for a patient population in the claimed age group and for a patient population in the claimed age group having type 2 diabetes is absent.

Applicants argue the examples described on pages 5-6 and Figures 1 and 2 of the disclosure show Applicants' possession of the invention through an animal model reasonably correlate to the claimed method.

Applicants' arguments are not persuasive. The rejection of claims 5 and 9-11 record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained and presently extended to include new claims 12-19. The skilled artisan in the diabetes art would reasonably require a more detailed description because those subjects encompassed in claim 5 having type 2 diabetes would reasonably be expected to have altered metabolic processes or rates, as compared to nondiabetics or to an adult population over the age of 18.

In the last Office Action claims 1-4 and 6-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Berger, S.P., WO 01/41763. It was asserted Berger

Art Unit: 1614

teaches a method of treating an overweight/obesity condition or an eating disorder, such as compulsive overeating, comprising administering pramipexole.

Applicants argue claim 5 was not previously included in the rejection set forth *supra*.

The rejection of record under 35 U.S.C. 103 is withdrawn.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.


If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-

Art Unit: 1614

0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 8, 2007


Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**